

REMARKS

Claims 1-6 and 8-16 are all the claims pending in the application.

Claims 1, 5, and 8 are amended in order to more clearly set forth the subject matter.

Claim 15 is amended to correct claim dependency, according to the cancellation of claim 7.

Claim 1 is further amended to include the features of claim 7, and claim 7 is canceled. Amended claim 1 may be supported by the disclosure, for example, at pages 8-9, Formula 2-4, page 15-19, Examples 1-9. Compounds of Formula 2-4 and Examples 1-9 clearly shows that Applicant have had possession of the block copolymer as defined in amended claim 1. No new matter is introduced. Entry and consideration of the amendment and allowance of the application are respectfully requested.

Claims 1-6 and 8-16 are patentable

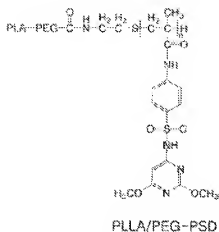
In the Office Action, claims 1-7 and 9 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Han et al. (Colloids & Surfaces A: Physiochem. Eng. Aspects, 2003, 49-59).

In the Office Action, claims 10-11 are rejected under 35 U.S.C. § 103(a) as being assertedly unpatentable over Han as applied to claim 1 above, further in view of Huang et al. (Macromol. Chem. Phys., 2003, pp. 1994-2001).

In the Office Action, claims 8 and 12-14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Han in view of Huang as applied to claims 1, 10, and 11 above, and further in view of Bae et al. (US Pat. No. 6,103,865).

Han is relied upon as teaching a block copolymer comprising poly(ethylene glycol) (PEG), poly(L-lactic acid) (PLLA; a biodegradable polymer; claims 4-5), and an oligomeric poly(sulfadimethoxine) (PSD; a sulfonamide-based oligomer) formed by coupling a PLA-PEG diblock copolymer with PSD (p. 51, scheme 1, (c)). The Office further asserts that Han's

Scheme 1 teaches that the PSD possesses a terminal amine group (claim 7) prior to forming the block copolymer. According to the Office, the resulting block copolymer is illustrated below:



Regarding claims 10-11, the Office further relies on Huang et al. (Macromol. Chem. Phys., 2003, pp. 1994-2001). The Office admits that Han does not teach a triblock or higher order multiblock copolymer. Huang is cited as teaching, in the field of block copolymer-based drug delivery, block copolymers with PEG, PLA, and poly(caprolactone) (PCL) segments (Abstract).

The Office asserts that PCL has a wide processing range (p. 1, Introduction, lines 8-12), and Huang's copolymers conserve the excellent thermal behavior inherent to PCL, providing a wide range of processing temperatures for thermal treatments (p. 2000, col. 2, lines 2- 6). The Office further contends that Huang's copolymers include a pentablock PLA-PCL-PEG-PCL-PLA, and a triblock mPEG-PCL-PLA (mPEG = monohydroxyl poly(ethylene glycol)) (p. 1995, Results and Discussion; p. 1996, Table 1).

With respect to claims 8 and 12-14, the Office admits that the Han fails to teach all elements of the claims. The Office cites Bae as disclosing a number of equivalent sulfonamides (cols. 3-4, Table 1).








In the Office Action, claims 15 and 16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Han as applied to claim 1 above, further in view of Shah (US Pat. No. 6,541,033).

Shah is relied upon as teaching, in the field of biodegradable block copolymer-based drug delivery, forming hydrogels from block copolymers comprising PLA or poly(lactide-co-glycolide) (PGLA) and PEG, for the sustained delivery of biologically active agents (Abstract). Shah further teaches that biodegradable block copolymers formed from PEGs with molecular weights ranging from 200 to 2000, and PLA or glycolic acid (GA) with molecular weights ranging from 400 to 5000 formed hydrogels (col. 2, line 67 — col. 3, line 3).

Applicant respectfully traverse for, at least following reasons.


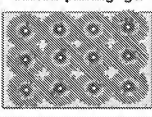
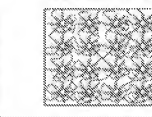

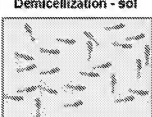

In Han, a sulfadimethoxine polymer (i.e., PSD) is directly bound to the polyethylene glycol (PEG) segment of the polymer. See Scheme 1(b) in Han. The structures of the block polymers of Han (“Cited Reference 1”) and the currently presented claim 1 are schematically shown in Table 1 below. In the currently presented claim 1, the OSM is bound to a hydrophobic block (e.g. the biodegradable polymer).

Table 1

Constitution		
Cited Reference 1	Claimed invention	
PLLA-PEG-PSD	PEG-PCLA-OSM	OSM-PCLA-PEG-PCLA-OSM
		
 : non-ionized sulfadimethoxine  : ionized sulfadimethoxine(PSD)	 : non-ionized sulfamethazine oligomer at low pH  : ionized sulfamethazine(OSM) at high pH	

The block copolymer comprising a hydrophobic block and a hydrophilic block, as disclosed in Han, forms a micelle. As shown in Table 2 below, the hydrophobic block (e.g., PLLA) of the polymer taught by Han forms a core of the micelle and the hydrophilic block (e.g., PEG) forms a shell of the micelle, respectively. At this time, the PSD bound to the hydrophilic block is positioned at a periphery of the formed micelle. Such a PSD, depending on pH of the environment, may be non-ionized and is micelle-aggregated, resulting in precipitated, or ionized to form a mono-micelle, as shown in Fig. 8 of Han. Such polymer as taught by Han cannot form a hydrogel because the micelle itself is not disentangled due to the binding position of the PSD (e.g., “the shell” of micelle).

[Table 2]

Effect	Cited Reference 1	Claimed invention	
	PLLA-PEG-PSO	PEG-PCLA-OSM	OSM-PCLA-PEG-PCLA-OSM
Low pH	 <p>Micelle aggregation & precipitation Water</p>	 <p>Micellar packing - gel</p>	 <p>Micellar network - gel</p>
High pH	 <p>water</p>	 <p>Demicellization - sol</p>	 <p>Demicellization - sol</p>

On the contrary, in the pH- and temperature sensitive block copolymer as defined in the currently amended claims of the application, sulfonamide-based oligomer (OSM) is directly bound to the biodegradable polymer segment in the PEG-co-biodegradable polymer block copolymer.

As shown in Table 2 above, the OSM bound to the hydrophobic block (e.g., the biodegradable polymer) exists in “the core” of the formed micelle.

Therefore, the OSM positioned at the core of micelle in the claimed invention is subjected to either the autonomous-sol transition or autonomous-gel transition, depending on the pH. In the autonomous-sol transition, the OSM is ionized, the physical entanglement of the micelle-type block polymer is released, and the linear polymer is dissolved in a solvent. In the

autonomous-gel transition, the OSM is non-ionized and the physical entanglement is generated due to the strong hydrophobic attractive force of the block copolymer.

However, the block copolymer of Han in which the PSD is directly bound to the PEG among the PLLA/PEG block copolymer cannot achieve “the effect of hydrogel formation according to the autonomous sol-gel transition” attained by the claimed invention.

As described above, the subject matter defined in currently amended claim 1 of the instant application is distinguishable from the teachings of Han 1 in their constitution, operational mechanism and the effect.

None of Bac, Huang, or Shah cures the above-described gap of Han. Therefore, it is believed that the rejection of claim 1 is not sustainable and its withdrawal is respectfully requested.

Claims 2-6 and 8-16, which directly or indirectly refer to claim 1 also should be patentable for at least their dependency of claim 1.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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Date: November 6, 2009